Remarks

Status of Claims

Upon entry of this Amendment, claims 12, 14-16, 28-32 and 39 are pending and are presented for prosecution. Claims 17-27 and 33-38 have been cancelled. Claims 1, 30 and 39 have been amended.

Claims Rejections: 35 U.S.C. §112, 2nd Paragraph

In the Office Action dated November 16, 2007, claims 12, 14-16, 28-32 and 39 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Regarding claim 12 step b) the Office Action asserts that "It is unclear how any type of assay, as recited in claim 1, would result in the identification of an agent that inhibits cellular levels **of** kinase activity."(see Office Action, page 3, emphasis added).

With regards to this statement and to clarify the rejection, the Applicants respectfully note that claim 1 has been cancelled and believe that the Office Action is referring to pending claim 12. Accordingly, the Applicants respectfully assert that claim 12, step b) did not and does not recite "the cellular level **of** kinase activity", rather claim 12 recites "cellular level **or** kinase activity" (see previous response filed August 14, 2007, emphasis added).

Regarding the preamble of claim 12, the Office Action asserts that " However, the preamble of the claim recites identifying agents that inhibit T lymphocyte development (i.e. any type of T cell development, including, for example, the "development" of a Th1 T cell response). It is unclear how the claimed method could be used to identify agents that inhibit other types of T cell development, other than the production of mature T lymphocytes from double positive T cells.".

The Applicants respectfully assert that according to MPEP 2111.02 (emphasis added),

> *"If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation")"*

Therefore, the Applicants respectfully assert that the preamble of claim 12 does not require the recitation of the claim limitation "mature T lymphocytes", as this limitation is set forth in the body of the claim.

In addition, regarding claim 12, the Office Action dated November 16, 2007, rejected claims 12 for lack of antecedent basis with respect to the limitation "the cellular level of kinase activity". Claim 12 has been amended to correct the antecedent basis for this limitation.

In view of the above, the Applicants respectfully request withdrawal of the rejection of claim 12 under 35 U.S.C. §112, second paragraph.

Regarding claim 14, the Office Action asserts that claim 14 is allegedly indefinite "since it broadens the scope of independent claim 12."(see Office Action, page 3). Specifically, the Office Action asserts that claim 12 "is already limited to identifying agents that inhibit the "cellular level" **of** kinase activity of IP3KB." (see Office Action, page 3, emphasis added).

As presented above, the Applicants respectfully assert that claim 12 step b) did not and does not recite "the cellular level **of** kinase activity", rather claim 12 recites "cellular level **or** kinase activity" (see previous response filed August 14, 2007, emphasis added). Therefore, the Applicants respectfully assert that claim 14 does not broaden the

scope of claim12. Accordingly, the Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. §112, second paragraph.

Regarding claims 30 and 32, the Office Action asserts that claims 30 and 32 are allegedly indefinite "in the recitation of an agent that decreases cellular levels of IP3KB."(see Office Action, page 3).

As presented above, the Applicants respectfully assert that claim 12 step b) did not and does not recite "the cellular level **of** kinase activity", rather claim 12 recites "cellular level **or** kinase activity" (see previous response filed August 14, 2007, emphasis added). The Applicants respectfully assert that the one or more agents identified in step (b) inhibit the cellular level of IP3KB **or** the one or more agents identified in step (b) inhibit the kinase activity of IP3KB.

Accordingly, the Applicants respectfully request withdrawal of the rejection of claims 30 and 32 under 35 U.S.C. §112, second paragraph.

Claims Rejections: 35 U.S.C. §112, 1st Paragraph

In the Office Action dated November 16, 2007, claims 12, 14-16, 28-32 and 39 were rejected under 35 U.S.C. §112, first paragraph, as the specification allegedly lacks written description of the claimed invention. The Office Action asserts that "the specification and the claims as originally filed do not provide support for the invention as now claimed". (see Office Action, page 4).

Specifically, the Office Action asserts the alleged lack of written description for "A method comprising identifying agents that inhibit the "cellular level of kinase activity" of IP3KB". (see Office Action, page 4).

As presented above, the Applicants respectfully assert that claim 12 step b) did not and does not recite "the cellular level **of** kinase activity", rather claim 12 recites "cellular level **or** kinase activity" (see previous response filed August 14, 2007, emphasis added). Further support that the requirements of 35 U.S.C. §112, first paragraph have been met for these claim elements is found in the Office Action, wherein the Office Action states (see page 4, emphasis added):

"Thus, while the specification discloses identifying an agent that inhibits the cellular level of IP3KB, ***or*** *the kinase activity, it does not disclose identifying an agent that inhibits the "cellular level" of kinase activity."*

Accordingly, the Applicants respectfully asserts, and the Office Action supports, that the specification as filed fully supports "A method comprising identifying agents that inhibit the "cellular level or kinase activity" of IP3KB", as recited in pending claim 12.

The Office Action further asserts the alleged lack of written description for "A method comprising testing an agent for "ability to inhibit T lymphocyte development in the thymus (Claim 39)."

The Applicants respectfully disagree, however, in order to expedite prosecution, claim 39 has been amended to recite "T lymphocyte development *in vivo* or *in vitro*." No new matter has been introduced with this amendment and support for this amendment can be found on page 21 of the specification as filed. Specifically, the specification states (emphasis added):

In some other embodiments, other than using an <u>in vitro</u> system such as thymic stroma cells, modulating activity on T cell development is examined using an animal harboring an IP3K (e.g., IP3KB). The animal can endogenously express an IP3K (e.g., mice expressing mouse IP3KB). Alternatively, a transgenic mouse containing human IP3KB gene <u>can be employed to study in vivo activity</u> of a test agent or a pre-screened IP3K modulator on T cell development. Typically, thymi from a transgenic mice administered with the IP3K modulating compound can be analyzed at various differentiation stage. For example, they can be analyzed by flow cytometry using antibodies against the different antigen markers of the T cells (e.g., antibodies against CD4 and CD8).

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 12, 14-16, 28-32 and 39 under 35 U.S.C. §112, first paragraph.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants believe all claims now pending in this Application are in condition for allowance, and reconsideration and allowance is respectfully requested.

A fee of $460.00 for a two (2) month extension of time is necessary in connection with this paper. It is believed that a total of $460.00 is due, however if this is incorrect and additional fees are due, or additional extensions of time are necessary to prevent abandonment of this application, then the U.S. Patent and Trademark Office is authorized to deduct any requisite fees from, or deposit any overpayment into, Deposit Account **No. 50-1885** referencing docket No. P1097US10

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is respectfully requested to contact the undersigned at the telephone number below.

Respectfully submitted,

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